APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

October Term, 1972

No. 72-2251

D. C. Docket No. CA-70-B-115

EPIFANIO REYES, Individually and as next Friend of Anita Reyes, a minor, *Plaintiff-Appellee,*

versus

WYETH LABORATORIES, a Division of American Home Products Corporation, a Delaware Corporation, *Defendant-Appellant.*

Appeal from the United States District Court for the Southern District of Texas

Before BROWN, Chief Judge, and WISDOM and AINSWORTH, *Circuit Judges.*

JUDGMENT

This cause came on to be heard on the transcript of the record from the United States District Court for the Southern District of Texas, and was argued by counsel:

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court that the judgment of the said District Court in this cause be, and the same is hereby, affirmed;

It is further ordered that defendant-appellant pay to plaintiff-appellee, the costs on appeal to be taxed by the Clerk of this Court.

July 31, 1974

Issued as Mandate

OPINION

[498 F.2d 1264 (5th Cir. 1974).]

Diversity action against defendant which marketed trivalent oral polio vaccine. The United States District Court for the Southern District of Texas, Reynaldo G. Garza, J., entered judgment for plaintiff, and defendant appealed. The Court of Appeals, Wisdom, Circuit Judge, held that where defendant which marketed unavoidably unsafe trivalent oral polio vaccine failed to provide parents of infant with either warning of risk of individualized medical judgment that treatment was necessary and desirable for infant, defendant was liable for failing to market its unavoidably unsafe product in such a way as to warrant [sic] parents of unreasonably dangerous condition.

Affirmed.

* * * * * *

Loyd E. Bingham, Jr., San Antonio, Tex., Eberle, Berlin, Kading, Turnbow & Gillespie, R. B. Kading, Jr., William J. McKlveen, Boise, Idaho, for defendant-appellant.

Daniel R. Murray, Chicago, Ill., for American Academy of Pediatrics, amicus curiae.

William J. Curran, Boston, Mass., for Conference of State and Territorial Epidemiologists, amicus curiae.

Rafael H. Flores, J. Perry Jones, McAllen, Tex., for plaintiff-appellee.

Before Brown, Chief Judge, and Wisdom and Ainsworth, Circuit Judges.

Wisdom, Circuit Judge:

This products liability case raises significant questions concerning the scope of a drug manufacturer's duty to warn ultimate consumers of dangers inherent in his product.

In May 1970, slightly more than two weeks after she had received a dose of Wyeth Laboratories' oral polio vaccine, eight-month-old Anita Reyes was diagnosed as having paralytic poliomyelitis. Epifanio Reyes, Anita's father, filed suit against Wyeth Laboratories, alleging that the live polio virus in the vaccine had caused Anita's polio and that Wyeth was liable for her injuries because it had failed to warn her parents of this danger. Wyeth contends that it is not liable for Anita Reyes's injuries under the products liability law of Texas. In addition, Wyeth raises numerous procedural and evidentiary questions. The case was tried to a jury. The jury answered special interrogatories (see Appendix A) and returned a verdict in favor of Reyes against Wyeth for the sum of $200,000.

I.

Twenty or thirty years ago poliomyelitis was a dread disease that especially attacked the very young. In 1952 alone, there were 57,879 reported cases of polio in the United States; 21,269 of these resulted in crippling paralysis to the victims. By 1970, when Anita Reyes contracted polio, the number of those stricken by polio had diminished dramatically; she was one of just 33 individuals to be afflicted during that year.[1] Credit for this precipitous decline must go primarily to the medical researchers who discovered the viral nature of the disease, and were able to isolate and reproduce the virus in an inactivated or an attenuated form. See Appendix B. But credit for this remarkable achievement must also be given to such laboratories as Wyeth, which processed the polio vaccine, and to massive federal-state public health programs for the administration of the vaccine.

---

[1] These statistics are drawn from official reports of the United States Public Health Service. See Morbidity and Mortality, Weekly Reports, Vol. 10, No. 53, Table 2, Page 4. (October 1962); Morbidity and Mortality, Weekly Reports, Vol. 19, No. 3, Table 2, Page 4 (August 1971).

On May 8, 1970, Anita Reyes was fed two drops of Sabin oral polio vaccine by eye-dropper at the Hidalgo County Department of Health clinic in Mission, Texas. The vaccine was administered to Anita by a registered nurse; there were no doctors present. Mrs. Reyes testified that she was not warned of any possible danger involved in Anita's taking the vaccine. Mrs. Reyes has a seventh grade education, but her primary language is Spanish. She signed a form releasing the State of Texas from "all liability in connection with immunization". The form contained no warning of any sort, and it is apparent from her testimony that she either did not read the form or lacked the linguistic ability to understand its significance. About fourteen days after the vaccine was administered, Anita Reyes became ill. On May 23, 1970, she was admitted to the McAllen (Texas) General Hospital, where her disease was diagnosed as Type I paralytic poliomyelitis. See Appendix B, foonote 59. As a result of the polio, at the time of trial Anita was completely paralyzed from the waist down, her left arm had become atrophied, and she was unable to control her bladder or bowel movements.

The vaccine given Anita Reyes in the Mission clinic on May 8, 1970 was part of a "lot", No. 15509, prepared by Wyeth.[2] Lot No. 15509 was trivalent oral polio vaccine that Wyeth had titered (mixed) from Types I, II, and III monovalent vaccine provided by Pfizer, Ltd. In response to an order placed by the Texas State Department of Health on December 23, 1969, Wyeth shipped 3500 vials of Lot No. 15509 vaccine to the State Health Department which in turn transferred 400 vials to the Hidalgo County

[2] The actual titering was performed by Wyeth Laboratories, Inc., a separately incorporated subsidiary of American Home Products, Inc. After this mixing process was complete the vaccine was shipped to American Home Products' unincorporated Wyeth Laboratories Division for distribution. Since both the division and the subsidiary are affiliates of appellant American Home Products, Inc. they are referred to interchangeably as "Wyeth" in the text.

Health Department. The jury found that vaccine from one of these vials was given to Anita Reyes. Included with every vial, each of which contained ten doses of vaccine, was a "package circular" provided by Wyeth which was intended to warn doctors, hospitals, or other purchasers of potential dangers in ingesting the vaccine. Mrs. Lenore Wiley, the public health nurse who administered the vaccine to Anita Reyes, testified that she had read the directions on this package insert, but that it was not the practice of the nurses at the Mission Health Clinic to pass on the warnings to the vaccinees or to their guardians. She testified that she gave Mrs. Reyes no warning before she administered the vaccine to Anita.

On October 7, 1970, Epifanio Reyes, individually and as next friend of his minor daughter, brought this action on theories of strict products liability, breach of warranty, and negligence. In his complaint he alleged that his daughter had contracted polio from the live virus in Wyeth's vaccine, and that Wyeth's failure to warn him or his wife that this might occur rendered it liable for Anita's injuries. Wyeth's main line of defense was that Anita's polio was not vaccine-induced at all. Wyeth produced experts who characterized virus isolated from a specimen of stool taken from Anita on the day after she was admitted to the hospital as "probably wild". This probability was increased, according to epidemiological testimony adduced on Wyeth's behalf,[3] by the fact that there was a polio "epidemic" in Hidalgo County at the time Anita fell ill. In effect, the jury rejected these theories in rendering a verdict for Reyes.

---

[3] "Epidemiology", the field of expertise of a number of Wyeth's experts, was defined in the defendant's trial brief as a "specialized field of medicine dealing with public health", which is "based on the observation of the occurrence of disease and thereafter, by statistical methods trying to arrive at a conclusion as to the possible source of the disease".

Wyeth asserts more than a score of separate grounds for reversal, each accompanied by extensive argument and citation. We have considered all of these contentions, but in this opinion we shall address only those challenges which we regard as raising substantial questions.

II.

We turn first to the substantive issues raised by this appeal. Our inquiry is bounded by the jury's finding that Wyeth's vaccine was the producing cause of Anita Reyes's polio, and by those principles of products liability law we conclude would be applied by the courts of Texas. Erie R. R. Co. v. Thompkins, 1938, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188.

The jury's finding that the Wyeth vaccine was responsible for Anita Reyes's polio is less a conclusion than a starting point. Texas courts may hold manufacturers of products which harm consumers liable for the injuries, but, of course, manufacturers are not insurers.[4] Texas courts recognize both tort and warranty theories of products liability.[5] This case was tried, briefed, and argued on appeal entirely on the tort theory of strict liability. Thus the differences between the two approaches,[6] and whatever

---

[4] Gravis v. Parke-Davis & Co., Tex.Civ.App. 1973, 502 S.W.2d 863, 868-869; Cudmore v. Richardson-Merrell, Inc., Tex.Civ.App. 1965, 398 S.W.2d 640, 644, writ ref. n. r. e., cert. denied, 1967, 385 U.S. 1003, 87 S.Ct. 705, 17 L.Ed.2d 542.

[5] See Borel v. Fibreboard Paper Products Corporation, 5 Cir. 1973, 493 F.2d 1076; reh. denied, 1973.

[6] Strict liability is "hardly more" than warranty stripped of its contractual trappings, Greeno v. Clark Equipment Co., N.D. Ind. 1965, 237 F.Supp. 427, 429. But if strict liability has supplanted warranty as the dominant doctrine, Grinnell v. Charles Pfizer & Co., Cal.Ct.App.1969, 274 Cal.App.2d 424, 79 Cal. Rptr. 369, 373, the outcome of product liability actions, especially where drugs are involved, does not appear to be a result of which theory is relied upon by the parties. See Davis v. Wyeth Laboratories, 9 Cir. 1968, 399 F.2d 121, 126; Merrill, Compensation for Prescription Drug Injuries, 59 Va.L.Rev. 1, 31 (1973).

contractual trappings of warranty have not been destroyed with the crumbling of the citadel of privity,[7] need not detain us. Rather, we turn to the theory of strict products liability as embodied in Section 402A of the Restatement (Second) of Torts (1965),[8] and approved by the Supreme Court of Texas in McKisson v. Sales Affiliates, Tex.Sup.Ct. 1967, 416 S.W.2d 787.[9]

---

[7] See Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099, (1960); Prosser, The Fall of the Citadel (Strict Liability to the Consumer) 50 Minn.L.Rev. 791 (1966).

[8] § 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

[9] The principle that sellers of food and drink for human consumption should be held to a high level of responsibility for any "corruption" in their wares is of medieval origin. Restatement of Torts, (Second) Section 402A, comment b; Prosser, The Assault Upon the Citadel (Strict Liability to the Consumer), 69 Yale L.J. 1099, 1103, (1960). There is no point in rehashing the history of the products liability doctrine. See, e.g., Professor Prosser's articles cited in Note 7, *supra;* Ray, Wade, P. Keeton, Noel, R. Keeton, and Whitmore, Products Liability—A Symposium, 19 Sw.L.J. 1 (1965); Traynor, note 11, infra; Greenman v. Yuba Power Products, Inc., Cal.Sup.1963, 59 Cal.2d 57, 27 Cal.Rptr.

Basically, Section 402A subjects to liability the seller or manufacturer of a product sold "in a defective condition unreasonably dangerous" to an ultimate user or consumer whose person or property is physically harmed by the product.[10] Moreover, one who places defective goods in the stream of commerce will be liable "to the user or consumer even though he has exercised all possible care in the preparation and sale of the product". Restatement (Second) of Torts, Section 402A, comment a. Yet imposition of liability is by no means automatic; the elements tacit or explicit in Section 402A's mandate must be demonstrated to the trial court's satisfaction before the burden of the consumer's loss will be imposed on the seller of the product:

> The plaintiff is faced with an arduous burden of proof. He must prove that: 1) the product in question was defective; 2) the defect existed at the time the products left the hands of the defendant; 3) that because of the defect the product was unreasonably dangerous to the user or consumer (plaintiff); 4) that the consumer was injured or suffered damages; 5) and that the defect (if proved) was the proximate cause of the injuries suffered.

Gravis v. Parke-Davis & Co., Tex.Civ.App.1973, 502 S.W.2d 863, 868. Although we do not embrace Gravis as the all-inclusive embodiment of Texas products liability law,

---

697, 377 P.2d 897; Escola v. Coca Cola Bottling Co., Cal.Sup.1944, 24 Cal.2d 453, 150 P.2d 436, 440 (Traynor, J., concurring). For recent articles on the Texas law of products liability, see Holford, The Limits of Strict Liability for Product and Manufacture, 52 Tex.L.Rev. 81 (1973); Freedman, The Texas Politics of Today's Products Liability, 5 St.Mary's L.J. 1 (1973); Schattman, A Cause of Action for the Allergic Consumer, 8 Hou.L.Rev. 827 (1971).

[10] Although the Restatement speaks in terms of "sellers", manufacturers of defective products are also swept within its ambit, even where, as here, another party performs the actual transfer of the offending product. See Section 402A, Comment f.

the framework it provides suggests a useful analysis for the issue of Wyeth's liability here.

All five elements, however, which constitute the Gravis requirements need not be discussed here. There can be no question that Anita Reyes was injured, so the fourth element is not in issue. Nor is the second, since the defect alleged, failure to warn by the manufacturer, is by definition the *manufacturer's* dereliction. Moreover, to find that the plaintiff proved the first element is to conclude that he proved the third, for properly understood, "defective condition" has no meaning independent of "unreasonably dangerous"; the two terms are essentially synonymous.[11] Thus if a product is unreasonably dangerous as marketed, the manufacturer may be held liable for injuries proximately caused by what he has produced, whether or not it was manufactured exactly as intended, that is without a production "defect".[12] We do not understand this approach to dispense with the principle that to prompt liability a product must reach the consuming public in a "defective condition". Rather, by rephrasing the defectiveness requirement in terms of "unreasonable danger", it becomes clear that the circumstances of marketing themselves can amount to a defect; the defect can be extrinsic to the product. All that we need determine here,

---

[11] Borel v. Fibreboard Paper Products Corp., 5 Cir. 1973, 493 F.2d 1076, 1087; Wade, Strict Tort Liability of Manufacturers, 19 Sw.L.J. 5, 14-15 (1965); Keeton Product Liability and the Meaning of Defect, 5 St.Mary's L.J. 30, 32 (1973). Justice Traynor goes still further. He has concluded that there is no single satisfactory definition of "defect" which will bear universal application. See Traynor, The Ways and Meanings of Defective Products and Strict Liability, 32 Tenn.L.Rev. 363, 367 (1965).

[12] See, e.g., Alman Bros. Farm and Feed Mill, Inc. v. Diamond Laboratories, Inc., 5 Cir. 1971, 437 F.2d 1295, 1302; Ross v. Up-Right, Inc., 5 Cir. 1968, 402 F.2d 943, 946; Helene Curtis Industries, Inc. v. Pruitt, 5 Cir. 1967, 385 F.2d 841, 855, cert. denied, 1968, 391 U.S. 913, 88 S.Ct. 1806, 20 L.Ed. 2d 652.

then, is first, whether the vaccine was unreasonably dangerous, and second, whether the showing of proximate causation was sufficient under Texas law.

a) Unreasonable Danger and the Duty to Warn

We begin the inquiry by asking whether the vaccine was unreasonably dangerous, that is, in a defective condition when Anita Reyes received it. It is clear, of course that the vaccine was not itself defective. Wyeth Vaccine Lot No. 15509 was exactly what its makers [13] and the Texas public health authorities intended it to be: trivalent live-virus Sabin oral polio vaccine. The live virus which the jury concluded caused Anita's poliomyelitis was not inadvertently included in the mixture.[14] Indeed, it is the presence of the living but attenuated Type I, II, and III viruses which makes the Sabin vaccine so effective [See Appendix B].

Although the living virus in the vaccine does not make the vaccine defective, it does make it what the Restatement calls an "unavoidably unsafe product", one which cannot be made "safe" no matter how carefully it is manufactured. Such products are not necessarily "*unreasonably* dangerous", for as this Court has long recognized in wrestling with product liability questions, many goods

---

[13] In a strict sense, Wyeth did not "make" or manufacture the vaccine which caused Anita Reyes's polio. The lot of trivalent vaccine was "titered" or mixed from separate strains of Type I, Type II, and Type III monovalent vaccines manufactured by Pfizer, Ltd. In the context of this case, however, we do not believe, nor did Wyeth argue, that this fact in any way affects its liability.

[14] Thus this action does not involve "defective" vaccine in the same sense as did Gottsdanker v. Cutter Laboratories, Cal.App. 1960, 182 Cal.App.2d 602, 6 Cal.Rptr. 320, an action in which the producer of Salk "killed virus" vaccine was held liable for the plaintiff's poliomyelitis caused by live virus inadvertently present in its vaccine.

possess both utility and danger. See, e.g., Ross v. Up-Right, Inc., 5 Cir. 1968, 402 F.2d 943, 946; Helene Curtis Industries, Inc. v. Pruitt, 5 Cir. 1967, 385 F.2d 841, 850, cert. denied, 1968, 391 U.S. 913, 88 S.Ct. 1806, 20 L.Ed.2d 652. Rather, in evaluating the possible liability of a manufacturer for injuries caused by his inevitably hazardous products, a two-step analysis is required to determine first, whether the product is so unsafe that marketing it at all is "unreasonably dangerous per se", and, if not, whether the product has been introduced into the stream of commerce without sufficient safeguards and is thereby "unreasonably dangerous as marketed."[15] In either case, the applicable standard, as formulated in the Restatement, is as follows: In terms of the user's interests, a product is "unreasonably dangerous" only when it is "dangerous to an extent beyond that contemplated by the ordinary consumer";[16] or, to phrase it in terms of the seller's responsibility, "so dangerous that a reasonable man would not sell the product if he knew the risk involved". See Borel v. Fibreboard Paper Products Corp., 5 Cir. 1973, 493 F.2d 1076, 1088; Helene Curtis Industries, Inc. v. Pruitt, 385 F.2d at 850; Wade, Strict Tort Liability of Manufacturers, 19 Sw.L.J. 5, 15 (1965).

---

[15] This "per se as marketed" distinction has been suggested by Dean Keeton. See e.g., Keeton, Products Liability—Inadequacy of Information, 48 Tex.L.Rev. 399, 406 (1970); Keeton, Products Liability and Meaning of Defect, 5 St. Mary's L.J. 30, 38 (1973).

[16] Comment i to Section 402A elaborates:

> I. *Unreasonably dangerous.* The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. . . . The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics.

In determining whether placing a commodity on the market is "unreasonably dangerous per se", the reasonable man standard of the Restatement becomes the fulcrum for a balancing process in which the utility of the product properly used is weighed against whatever dangers of harm inhere in its introduction into commerce. Obviously, use of an unavoidably unsafe product always presents at least a minimal danger of harm, but only if the potential harmful effects of the product—both qualitative and quantitative—outweigh the legitimate public interest in its availability will it be declared unreasonably dangerous per se and the person placing it on the market held liable.[17] Applying this standard here, the scales must tip in favor of availability. The evil to be prevented—poliomyelitis and its accompanying paralysis—is great. Although the danger that vaccinees may contract polio is qualitatively devastating, it is statistically miniscule. On balance then, marketing the vaccine is justified despite the danger.

Since Sabin oral polio vaccine is not "unreasonably dangerous per se", we move to the second step of our analysis to determine whether it is "unreasonably dangerous as marketed", for to conclude that the maker of an unavoid-

---

[17] Professor Wade suggests a rather more complex calculus, with no fewer than seven variables:

> Factors involved in making this determination include, among others, the following: (1) the usefulness and desirability of the product, (2) the availability of other and safer products to meet the same need, (3) the likelihood of injury and its probable seriousness, (4) the obviousness of the danger, (5) common knowledge and normal public expectation of the danger (particularly for established products), (6) the avoidability of injury by care in use of the product (including the effect of instructions or warnings), and (7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

19 Sw.L.J. at 17. Without elaborating, we believe that however scrutinized, the oral polio vaccine was not "unreasonably dangerous per se", for the reasons marshaled in the text

ably unsafe product did not act unreasonably in placing it on the market is not to relieve him of the responsibility to market it in such a way as to prevent unreasonable danger. In the case of a product such as Sabin oral polio vaccine, this translates into a duty to provide proper warnings in selling the product. As comment k to Section 402A instructs, an unavoidably unsafe product is neither defective nor *unreasonably* dangerous if such a product is "properly prepared, and is accompanied by proper directions and warning".[18] Consequently, the Restatement requires a seller who has reason to believe that danger may result from a particular use of his product to provide adequate warning of the danger in order that the product's potential

---

[18] Comment k provides:

> k. *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

for harm may be reduced. Failure to give such a warning when it is required will itself present a "defect" in the product and will, without more, cause the product to be "unreasonably dangerous as marketed".[19]

Issue is joined then, on the question whether Wyeth was under a duty to warn the parents of Anita Reyes that there was a possibility, however remote, that she might contract polio from the drug designed to immunize her.

---

[19] See Ford Motor Co. v. Russell & Smith Ford Co., Tex. Civ.App.1971, 474 S.W.2d 549, no writ hist.; see also, Rumsey v. Freeway Motor Minimax, Tex.Civ.App.1968, 423 S.W.2d 387, 393, no writ hist. Restatement (Second) of Torts, Section 402A, Comments h and j (1965).

Comment h provides in pertinent part:

> h. A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable. Where, however, he has reason to anticipate that danger may result from a particular use, as where a drug is sold which is safe only in limited doses, he may be required to give adequate warning of the danger (see Comment j), and a product sold without such warning is in a defective condition.

Comment j provides:

> j. Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger.

If such a duty existed, the vaccine was "defective" and unreasonably dangerous as marketed, for such cautions as Wyeth advanced did not, and were not intended to, reach the Reyes family. See Davis v. Wyeth Laboratories, Inc., 9 Cir. 1968, 399 F.2d 121, 129.

Wyeth does not deny that its vaccine is "unavoidably unsafe", or contend that it was unaware of the danger. Rather, the appellant contends that if it had a duty to warn at all, that duty was discharged by the warning contained on the package insert which accompanied the vials of vaccine sold to the Texas State Department of Health. This is so, Wyeth asserts, because the Sabin trivalent oral polio vaccine in issue here is a "prescription drug", and those who prepare such drugs are not required to warn the ultimate consumer. If the warning to the dispensing physician or authorities (here the Texas and Hidalgo County Public Health Departments) was adequate, Wyeth is not liable for any harm caused by the vaccine. Resolution of these contentions is crucial; Wyeth concedes in its brief that "[s]ince it is undisputed that Wyeth did not warn Reyes, but only the Texas State Department of Health, a finding that the vaccine was not a prescription drug establishes as a matter of law the defectiveness of the vaccine for purposes of a prima facie case in strict products liability."

We cannot quarrel with the general proposition that where *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use.[20] This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods

---

[20] See, e.g., Basko v. Sterling Drug, Inc., 2 Cir. 1969, 416 F.2d 417, 426; Davis v. Wyeth Laboratories, 9 Cir. 1968, 399 F.2d 121, 130; Merrill, Compensating for Prescription Drug Injuries, *supra* note 6, at 91. This approach has been adopted by at least one Texas court. See, Gravis v. Parke-Davis, Inc., Tex.Civ.App.1973, 502 S.W.2d 863, 870.

must warn foreseeable ultimate users of dangers inherent in his products. See Restatement (Second) of Torts, Section 388 (1965). Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.[21]

Although there is no question that Sabin oral vaccine is licensed for sale only as a prescription drug,[22] the district court, in its charge to the jury, noted that the vaccine was not administered as a prescription drug at the Mission Clinic. The court charged: "if you [the jury] find that a warning should have been given, the warning had to be given to Anita and her parents, not to Mrs. Wiley, that Public Health nurse, somebody else . . . The ultimate consumer is the one that had to be warned." The district court apparently based this instruction on the leading federal case in the area, Davis v. Wyeth Laboratories, 9 Cir. 1968, 399 F.2d 121. In *Davis,* the plaintiff had allegedly contracted polio from Wyeth oral vaccine distributed at a public clinic. The Ninth Circuit held that where no indi-

---

[21] See, Schenebeck v. Sterling Drug, Inc., 8 Cir. 1970, 423 F.2d 919, 922; Davis v. Wyeth, *supra* note 20, 399 F.2d at 130; Sterling Drug, Inc. v. Cornish, 8 Cir. 1966, 370 F.2d 82, 85; Gravis v. Parke-Davis & Co., *supra,* note 20, 502 S.W.2d at 870, 56 Geo.L.J. 1016, 1018 (1968).

[22] See, Title 42 U.S.C. § 262(a); 42 C.F.R. §§ 73.200-73.240, 73.1020-73.1028.

vidualized medical judgment intervenes between the manufacturer of a prescription drug and the ultimate consumer, "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning." 399 F.2d at 131. Where there is no physician to make an "individualized balancing . . . of the risks", the Court reasoned, the very justification for the prescription drug exception evaporates. Thus, as in the case of patent drugs sold over the counter without prescription, the manufacturer of a prescription drug who knows or has reason to know that it will not be dispensed as such a drug must provide the consumer with adequate information so that he can balance the risks and benefits of a given medication himself. Moreover, just as the manufacturer cannot make this choice for its ultimate consumers, it cannot allow its immediate purchaser to choose for them. In sum, then, the manufacturer is required to warn the ultimate consumer, or to see that he is warned. 399 F.2d at 131.

Wyeth does not resist the Ninth Circuit's holding in *Davis*, but asserts that the instant case can be distinguished on four grounds. First, the appellant argues, Davis received his vaccine during a mass immunization program, whereas Anita Reyes ingested her vaccine at her parents' request. Second, Wyeth stresses the fact that Davis received his vaccine from a pharmacist, but Reyes' was administered by a public health nurse. Third, Wyeth's active participation in the mass immunization program involved in the *Davis* case is contrasted to its relatively passive role here. Finally, Wyeth urges that unlike the situation in *Davis*, here it had no knowledge that the vaccine would not be administered as a prescription drug.

None of these asserted grounds for distinguishing *Davis* justifies a different result here. The first two arguments are admittedly distinctions between *Davis* and the instant controversy, but they have no bearing on the *rationale* of the *Davis* opinion. Whether vaccine was received during

a mass immunization or an on-going program, whether it was administered by nurse or pharmacist, it was, in both these cases, dispensed without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception. The third and fourth asserted bases for distinguishing *Davis* from this case are essentially the same: Wyeth took no active part in the vaccination process here, and did not know that its vaccine would be dispensed without procedures appropriate for distribution of prescription drugs.

Were we to conclude that Wyeth neither knew nor had reason to know that its vaccine would be dispensed without prescription drug safeguards, we might be required to hold that the *rationale* in *Davis* is inapplicable here. But Wyeth had ample reason to foresee the way in which its vaccine would be distributed. A drug manufacturer is held to the skill of an expert in his field, and is presumed to possess an expert's knowledge of the arts, materials, and processes of the pharmaceutical business.[23] Included in such expertise must be a familiarity with practices and knowledge common in the drug industry as to distribution and administration of pharmaceutical products.

Neal Nathanson, Professor of Epidemiology at the Johns Hopkins University School of Public Health and a witness for Wyeth testified that it was common knowledge in the drug industry that "a great majority" of vaccinees receive their Sabin vaccine in mass administrations or county clinics manned at least in part by volunteers. Moreover, Dr. Nathanson agreed that it was well known that such clinics were stocked primarily by sale of vaccine to state health departments. These clinics, as Wyeth must be presumed to know, dispense Sabin vaccine to all comers in an

---

[23] See, e.g., Wright v. Carter Products, Inc., 2 Cir. 1957, 244 F.2d 53; Johnston v. Upjohn Co., Mo.Ct.App.1969, 442 S.W.2d 93, 96; Bine v. Sterling Drug Co., Mo.Sup.Ct.1968, 422 S.W.2d 623, 628; 2 F. Harper & F. James, The Law of Torts § 28.4 (1956); 5 San Diego L.Rev. 422, 427, n. 18 (1968).

"assembly line" fashion; there is often neither time nor personnel to make an "individualized medical judgment" of the vaccinee's needs or susceptibilities. See Davis v. Wyeth, *supra,* 399 F.2d at 131; 56 Geo.L.J. 1016, 1017 (1968); 5 San Diego L.Rev. 422, 428 (1968).

Viewed in this light, the present controversy, however it differs from *Davis* factually, invites application of the *Davis* principles, and the conclusion that Wyeth was under a duty to warn Anita Reyes's parents of the danger inherent in its vaccine. Wyeth knew or had reason to know that the vaccine would not be administered as a prescription drug, and therefore was required to warn foreseeable users, or see that the Texas Department of Health warned them. See Davis v. Wyeth, *supra,* 399 F.2d at 131; cf. Helene Curtis Industries v. Pruitt, *supra,* 385 F.2d at 861. Wyeth's failure to warn was a breach of its duty and made the vaccine "defective"—hence "unreasonably dangerous" —as marketed.

Before moving to a consideration of causation, we pause to analyze two possible arguments, one raised by Wyeth and one not, which appear to add further conceptual problems in the "duty to warn" area.

The first may be disposed of quickly. Wyeth contends that whatever its duty to warn, Mrs. Reyes assumed the risk that her daughter might contract polio, or effectively released Wyeth, by signing a "release" purporting to excuse the State of Texas from liability. Wyeth does not explain how signing a form releasing the State could excuse Wyeth from performing a duty to warn imposed on it by law, other than to cite the "unity of release" rule, apparently under the assumption that the State of Texas was its agent. Since we decline to adopt the district court's conclusion that Texas was the agent of Wyeth in administering the vaccine, we need not consider Wyeth's contention that the release signed by Mrs. Reyes also applied to it. Moreover, although we agree that assumption of risk is a proper

defense to a product liability action in Texas (see Borel v. Fibreboard Paper Products Corp.) one cannot assume a risk of which he is unaware. Shamrock Fuel & Oil Sales Co. v. Tunks, Tex.Sup.1967, 416 S.W.2d 779, 786 and n. 8. Since Mrs. Reyes was not cognizant of the danger inherent in the vaccine, she could not have assumed the risk of its use.

Somewhat more troubling is a line of Texas cases involving unusual allergic reactions to potentially dangerous products sold without a warning. These decisions may be read for the proposition that only if the product, properly prepared, will harm a substantial number of people will the manufacturer be held liable for his failure to warn. See C. A. Hoover & Son v. O. M. Franklin Serum Co., Tex.Sup. 1969, 444 S.W.2d 596, 598; Alberto-Culver Co., v. Morgan, Tex.Civ.App.1969, 444 S.W.2d 770, 776-777, writ ref. n. r. e.; Cudmore v. Richardson-Merrell, Inc., Tex.Civ.App. 1966, 398 S.W.2d 640, 644,[24] writ ref. n. r. e., cert. denied, 1967, 385 U.S. 1003, 87 S.Ct. 705, 17 L.Ed.2d 542.

Essentially these are foreseeability cases; the element they would require to invoke strict liability doctrines is foreseeability. In these cases, the manufacturer not only marketed the unavoidably unsafe product without adequate warning and with the knowledge that it was inherently dangerous, but the danger to any individual consumer was sufficiently significant and knowable that (1) the manufacturer was cognizant of a need to warn so as to prevent injury and (2) the consumer might or could have altered his conduct in such a way as to lessen or avoid the danger. This ancipital coin of foreseeability is the currency of these Texas cases. What they seek to avoid is the imposi-

[24] There is considerable and respectable authority at variance with the Texas position that immunizes a drug manufacturer from liability to an idiosyncratic consumer. See, e.g., Davis v. Wyeth Laboratories, *supra* note 20, 399 F.2d at 129; Sterling Drug, Inc. v. Cornish, *supra* note 21, 370 F.2d at 85.

tion of liability for "abreactions", hypersensitive allergic reactions so unique that the class of persons *exposed* to the risk is miniscule. See Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d at 644. In such cases, warnings would be meaningless, since the manufacturer can convey nothing meaningful to the allergic consumer unless the latter knows he has the allergy. Without such knowledge, the consumer is apt to assume that he is not a member of the minute susceptible class and to disregard the warning. See Alberto-Culver Co. v. Morgan, 444 S.W.2d at 777. Thus with the utility of warning limited and the susceptible class minute, the manufacturer is not required to foresee that anyone will suffer an allergic reaction to his product, and is not held liable.

To the instant analysis, these principles present no dilemma, for the effect of the Sabin oral vaccine upon those who contract polio from it cannot fairly be styled an "abreaction".[25] Although the danger of vaccine-induced polio to any one individual is small, the risk appears to be distributed evenly among that substantial segment of the population that is not naturally immune to polio. This is so because the behavior of polio virus in those who contract the disease seems to suggest more a reversion to virulence by the virus than a sensitivity in the vaccinee. Thus, if an individual is a member of the significant susceptible class, and his case should be one of those rare instances in which the vaccine strain reverts to virulence, he may contract polio. This is not a case like *Cudmore*, then, where the "appellant belongs to a class of people not appreciable in number who are allergic to the drug," and in which a warning would have been futile. 398 S.W.2d at 644. Rather,

---

[25] For a more detailed discussion of various types of allergic reactions, and their legal significance, see, Merrill, Compensating for Prescription Drug Injuries, 59 Va.L.Rev. 1 (1973); Schattman, A Cause of Action for the Allergic Consumer, 8 Houston L.Rev. 827 (1971); Rheingold, Products Liability—The Ethical Drug Manufacturer's Liability, 18 Rutgers L.Rev. 947 (1964).

proper warnings here would be addressed to a sizeable group and would be designed to alert each of its members that although the incidence of vaccine-induced polio is minute, he does belong to a substantial class, an unpredictible few of which could contract polio from the vaccine. In light of such factors, the Texas "abreaction" cases cannot dilute Wyeth's duty to warn here. This view coincides with the objective of Section 402A to protect the consumer by *his* standards of reasonableness in determining the manufacturer's duty.

b) Proximate Cause

Having concluded that Wyeth had a duty to warn Anita Reyes, and that, dispensed without a warning, the vaccine was unreasonably dangerous, we now turn to Wyeth's objections to the trial court's not instructing the jury and not submitting an interrogatory on the issue of "proximate cause".

As Wyeth correctly contends, there are two causation issues in most product liability cases. The first is that of "producing cause": Was the defendant's product the cause-in-fact of the plaintiff's injuries? More specific is the question posed under the rubric of proximate causation: Did the plaintiff's injuries result from the alleged "defect" in the defendant's product? Unless the jury is given an opportunity to pass upon both issues, Wyeth urges, the plaintiff has not made out a prima facie case of product liability. If Wyeth is correct, reversal is required, for the trial judge made it clear that he did not believe proximate cause to be an issue in this controversy, and neither instructed the jury nor submitted an interrogatory on the question.[26] We cannot concur in Wyeth's premise,

---

[26] A colloquy on requested instructions between two attorneys for Wyeth and the court make the court's position on the need to prove proximate cause clear:

MR. KADING: Then we believe that there should be an interrogatory between number five and number six which makes

however. The submission of interrogatories accompanying a general verdict is within the discretion of the trial court.[27] Moreover, although an instruction on proximate cause is appropriate in most products liability cases, a jury finding on the question was not required here.

As a general proposition, both Texas Courts and this Court have required that the plaintiff in a product liability suit prove not only that his injuries were caused by the defendant's product, but that they resulted from an alleged defect in the product.[28] Leading commentators have con-

---

this a matter of proximate cause. In other words, to the effect asking the jury to find whether or not the failure to warn was proximate cause of the consequences to this child in view of the fact that even with warning they may have proceeded with immunization, and in fact did so even after immunization here. And I suppose for the purposes of the record I ought to ask the court to in effect resubmit interrogatories that we submitted to the court before.

MR. MCKLVEEN: And I think as to interrogatory number two dealing with producing cause rather than causal cause the jury should be instructed that they should find—have to find first—the product was not fit for the purpose for which it was intended in order to get into proximate cause rather than producing cause.

THE COURT: Well, I have already stated at the beginning what my feelings are in this case, that if there was a risk, if she did get it from the vaccine, and you all failed to warn them about the risk so that they could make a choice, that you are liable regardless. And I think I have enough answers here.

MR. FLORES: We have no objections.

THE COURT: I wouldn't mind giving the question of proximate cause but I don't think it is necessary and you all tell me that you don't want it in there.

[27] The submission of interrogatories accompanying a verdict is sanctioned by Fed.R.Civ.P. 49(b).

The trial judge's decision to submit the issues to the jury pursuant to Rule 49(b) is within his discretion, and will be reversed only upon a clear showing of abuse. See Abernathy v. Southern Pacific Co., 5 Cir. 1970, 426 F.2d 512.

[28] E.g., Technical Chemical Co. v. Jacobs, Tex.Sup.1972, 480 S.W.2d 602, 605; Kritser v. Beech Corp., 5 Cir. 1973, 479 F.2d 1089, 1091.

curred.[29] Yet the rule in Texas that proximate cause must be specifically proved in products liability cases is not immutable. In some circumstances, proximate cause may be inferred as a matter of law or as a matter of fact. Procter & Gamble Mfg. Co. v. Langley, Tex.Civ.App.1967, 422 S.W.2d 773, writ dismissed, want of jurisdiction. In other cases, an instruction on producing cause which omits a consideration of proximate cause may be sufficient. C. A. Hoover and Son v. O. M. Franklin Serum Co., Tex.Sup. 1969, 444 S.W.2d 596, 598. We believe, in light of the holding in *Hoover* and crucial dicta in Technical Chemical Co. v. Jacobs, Tex.Sup.1972, 480 S.W.2d 602, that to have omitted a specific proximate cause instruction here was not reversible error.

Hoover was an action against a serum manufacturer by the owners of 25 Hereford calves which had become desperately ill after having been innoculated with the defendant's antibiotic. The trial resulted in a verdict and judgment for the plaintiffs, which was reversed and remanded by the court of civil appeals because the trial court had submitted a special issue on "producing cause" rather than "proximate cause", "and had thus failed to require the element of foreseeability". The Supreme Court of Texas reversed the court of appeals, and held that where, as here, the injury's foreseeability was not in issue, the "producing cause" instruction was sufficient. Much of the Supreme Court's brief opinion is spent in distinguishing the issue presented in *Hoover* from that considered in Cudmore v. Richardson-Merrell, Inc. *Cudmore* required that the jury consider whether the defendant's product was the "proximate cause" of the plaintiff's injuries rather than merely whether it was the "producing cause", since the latter inquiry "omits entirely the element of foreseeability. . . ."

---

[29] E.g., Keeton, Products Liability—Inadequacy of Information, 48 Tex.L.Rev. 398, 413 (1970); Wade, Strict Tort Liability of Manufacturers, 19 Sw.L.J. 5, 22, 25 (1965).

The *Hoover* court distinguished *Cudmore* on the ground that it involved an "abreaction" to a "pure drug" and thus foreseeability was a crucial issue. In such a case, a "proximate cause" instruction is required. In *Hoover*, however, all twenty-five innoculated cattle fell ill or died. The jury found that the cause of this widespread illness was not an unforeseeable abreaction. Thus, concluded the Texas Supreme Court, foreseeability was not in issue, and no proximate cause instruction was required.

The *Hoover* rationale is applicable to the instant controversy. Although this is, in a sense, a "pure drug" case like *Cudmore*, as we have pointed out above, it involves no "abreaction". As we have also concluded earlier, foreseeability—both as to the possibility of injuries and the manner of dispensing the drug—is not really in issue. In *Hoover*, "foreseeability" was found by the jury; here it was established as a matter of law. *Hoover* was not, of course, a "failure to warn" case. The defect involved was intrinsic to the serum which felled the plaintiff's cattle, a fact which may differentiate *Hoover* from extrinsic defect cases where the product and defect are separable. See Keeton, Products Liability—Problems Pertaining to Proof of Negligence, 19 Sw.L.J. 26, 33 (1965). Yet language in Technical Chemical Co. v. Jacobs, the recent Texas Supreme Court examination of failure to warn, convinces us that even in this area, a producing cause instruction will suffice in the circumstances of this case.

Technical Chemical involved a suit against the manufacturer of a can of freon which exploded in the plaintiff's hand as he attempted to put its contents into the air conditioning unit of his automobile. It was apparent from testimony adduced at trial that Jacobs, the plaintiff, inadvertently and mistakenly attached a hose from the "high" pressure side of his air conditioning compresser to the can of freon, rather than joining a hose from the "low" pressure side, which was the proper procedure. The can exploded, a possible result which the directions on the can's label did

not mention. Jacobs admitted, however, that *he had not read* the directions on the can's label. In light of this fact, the jury refused to find that Technical Chemical's failure to warn was a cause of Jacobs' injuries.

In affirming the trial verdict, the Supreme Court of Texas held that it was "incumbent upon the plaintiff to secure a jury finding that the faulty labeling was a cause of the injury". This he had not done. 480 S.W.2d at 605. Moreover, a plaintiff who had not read such directions as were provided could hardly expect the court to conclude that the manufacturer's failure to provide further warnings caused his injury as a matter of law.

Although much of the *Technical Chemical* opinion speaks in absolute terms of requiring proof that the defect caused the plaintiff's injuries, it also recognizes how "speculative" testimony in this type of case is likely to be and suggests an alternative approach, a legal "presumption that an adequate warning would have been read". 480 S.W.2d at 606. See Restatement (Second) of Torts, § 402A, comment j. As the court explained:

> Such a presumption works in favor of the manufacturer when an adequate warning is present. Where there is no warning, as in this case, however, the presumption that the user would have read an adequate warning works in favor of the plaintiff user. In other words, the presumption is that Jacobs would have read an adequate warning. The presumption, may, however, be rebutted if the manufacturer comes forward with contrary evidence that the presumed fact did not exist.

480 S.W.2d at 606.

Read together, *Hoover* and *Technical Chemical* suggest a test for cases such as the one now before the Court: Where a consumer, whose injury the manufacturer should have reasonably foreseen, is injured by a product sold without a required warning, a rebuttable presumption will arise that the consumer would have read any warning provided by

the manufacturer, and acted so as to minimize the risks. In the absence of evidence rebutting the presumption, a jury finding that the defendant's product was the producing cause of the plaintiff's injury would be sufficient to hold him liable.

Such a test makes sense in this case. The jury found that the defendant's polio vaccine caused Anita Reyes's polio. Testimony by her mother as to what she would have done, had proper warnings been provided, would have been both speculative and self-serving. Thus we turn to the *Technical Chemical* presumption that a warning, had it been given, would have been heeded. Buttressing the presumption that Mrs. Reyes might have taken preventive steps is the testimony of Reyes' expert, Dr. Ramiro Casso, that some pediatricians in Hidalgo County, at least by the time of trial, had begun administering killed-virus vaccine to infants in order to build up their level of antibodies before feeding them the live-virus drug. Tending to rebut the presumption that Mrs. Reyes would have behaved differently had she been warned was the fact that she twice returned to the Mission Clinic for further doses of vaccine, even after Anita contracted polio. Yet it is patent from her testimony that Mrs. Reyes had not, even then, been informed of the danger of the polio vaccine, and did not in fact understand what medication Anita was to receive.[39] The legal presumption

---

[39] On cross-examination, Mrs. Reyes was asked about a card she had signed at the clinic which indicated that she had returned after the onset of Anita's illness:

Q. And did you read that before you signed it?
A. No, I didn't read it. I just signed it.
Q. I notice some other entries. Have you taken Anita back for further immunization since the date of—
A. Yes.
Q. What has she been immunized for or vaccinated for since May 8, 1970?
A. I don't know. They just put it on there.
Q. You just take her and they do it?
A. Yeah. They are the ones that know what they are going to put next.

suggested by the *Technical Chemical* opinion thus operates here to provide the final element necessary to hold Wyeth Laboratories liable for Anita Reyes' poliomyelitis. Aware of its unavoidable dangers and cognizant that it foreseeably would not be dispensed as a prescription drug, Wyeth nonetheless failed to warn Mrs. Reyes that its vaccine could cause polio in some few of the millions receiving the medication. Administered without a warning, the vaccine was "defective", hence unreasonably dangerous. According to the test we have distilled above, we must assume in the absence of evidence to the contrary that Anita's parents would have acted on the warning, had it been given. Perhaps this would have prevented her polio. It unquestionably would have avoided Wyeth's liability.

III.

Having concluded that Wyeth was properly held liable under substantive law, we turn to procedural matters, specifically to Wyeth's objections to the admission or exclusion of various testimony and exhibits, and to its assertion that the evidence was insufficient to support the verdict for the plaintiffs.

(a) The Impeachment of Dr. Fox

Among the medical experts called to testify in Wyeth's behalf was Dr. John D. Fox, Associate Dean and Professor of Epidemiology at the University of Washington School of Public Health. On cross-examination, after Dr. Fox had testified that Type III polio vaccine was less stable than either Type I or Type II, counsel for the plaintiffs attempted to impeach his testimony by reference to an uncertified transcript of an earlier trial in which Dr. Fox had been called as a witness in Wyeth's behalf. There Dr. Fox had testified that Type I polio vaccine was "unstable", with reference to its "antigenic character", and Reyes's counsel attempted to show that this earlier testimony contradicted Dr. Fox's testimony as to Type I's stability here. Upon further inquiry, however, Dr. Fox

was apparently successful in explaining that his previous statement as to Type I's instability dealt only with its "antigenic instability," that is, its tendency to become an "unvaccine-like" strain, whereas his comments on the instability of the Type III virus related to its propensity to cause polio in monkeys or man. On appeal, Wyeth contends that this line of questioning was improper and requires reversal, both because the testimony of an expert cannot be impeached through the use of prior inconsistent statements and because no proper foundation was laid.

We concur in Wyeth's conclusion that the law of Texas governs the conduct of this type of impeachment. See Wright, Law of Federal Courts, § 94 at 412-15.[31] We cannot, however, read the cases cited by the appellant as prohibiting cross-examination of expert witnesses through the use of prior inconsistent testimony. Texas does not bar impeachment of a *lay* witness through the use of testimony given by him at a former trial.[32]

---

[31] Professor Charles A. Wright suggests that it may be necessary to look beyond the stark dictates of F.R.Civ.P. 43(a) to determine whether federal or state evidentiary standards ought to be invoked in a given situation. Three types of evidentiary rules exist, he postulates, and the choice between federal and state tests ought be made on the basis of which *type* of rule a given bit of evidence invokes. First are those rules which are of a merely "housekeeping" nature; here federal standards can be applied without hesitation. Next are rules that not merely regulate evidence, but are closely intertwined with the substantive rights of the parties. Here state standards should be honored. Finally, come state evidentiary rules specifically designed to effectuate an extrinsic state policy. So long as the rules are successful in achieving that end, they should be honored. The impeachment of an expert witness challenged here, was, we conclude, so tied to Wyeth's attempt to prove its theory of the case that substantive rights are at stake and Texas impeachment standards must govern. See, C. Wright, Law of Federal Courts, § 94 at 412-415.

[32] Gabel v. Blackburn Operating Corp., Tex.Civ.App.1969, 442 S.W.2d 818, 819, no writ hist.; Flowers v. Central Power and Light Co.; Tex.Civ.App.1958, 314 S.W.2d 373, writ ref. n. r. e.

It is difficult to understand why this impeachment technique ought not be available when the witness is an expert rather than a layman. Indeed, it might be argued that prior inconsistency is a particularly appropriate weapon for attacking expert testimony, since demonstration of the inconsistency is designed not to show that the expert has erred, but that he is *capable* of error. See Cirilo v. Cook Paint and Varnish Co., Tex.Civ.App.1972, 476 S.W.2d 742, 748, writ ref. n. r. e. Not surprisingly, then, Texas courts endorse far-ranging cross-examination generally, and have permitted particularly wide latitude in the interrogation of an adversary's expert. See Davidson v. County of Harris, Tex.Civ.App.1970, 454 S.W.2d 830, 832, writ ref. n. r. e. Thus in Hutson v. State, Tex.Cr.App.1956, 164 Tex.Cr.R. 24, 296 S.W.2d 245, 247-248, the prosecution was permitted to impeach the testimony of a county sheriff as to the defendant's intoxication, by introducing a tape recording (made shortly after the defendant's arrest) in which the sheriff voiced an opinion contrary to that offered at trial. Also permitted in cross-examination of real estate experts has been reference to earlier inconsistent appraisals of land, the value of which is in issue.[33]

A similar standard should apply to expert medical testimony. Wyeth concedes that a cross-examiner may properly inquire whether a medical expert has previously testified on behalf of the party for whom he offers testimony. But, Wyeth urges, any further foray into prior testimonial assertions is forbidden by Texas law. We do not so read the Texas cases. To be sure, no inquiry into the *correctness* of opinions expressed at earlier trials is proper;[34] but

---

[33] See City of Garland v. Stevener, Tex.Civ.App.1970, 462 S.W. 2d 67, 69, writ ref. n. r. e.; City of Dallas v. Holcomb, Tex.Civ. App.1964, 381 S.W.2d 347, 350, writ ref. n. r. e.

[34] Horton v. Houston & T. C. Ry. Co., 1907, 46 Tex.Civ.App. 639, 103 S.W. 467, 469, writ ref.; Traders & General Ins. Co. v. Robinson, Tex.Civ.App.1949, 222 S.W.2d 266, 269, writ ref.

an inconsistency, if there is one, may be demonstrated. As we noted earlier, the purpose of such impeachment is not to demonstrate that the expert has erred, but that he is capable of error. An expert in medicine is not exempt from the use of prior testimony to prove his fallibility.

Wyeth also urges that even if permitting the impeachment was proper, counsel for Reyes failed to lay the proper foundation for the impeachment and that therefore the court erred in allowing the cross-examination to proceed. Texas courts and this Circuit have held that to impeach a witness by showing a prior inconsistent statement, "a foundation must first be laid by asking the witness whether he made the statement, giving him an opportunity to admit or deny the statement, to correct his testimony, and to explain the apparent contradiction".[35]

Yet it is Reyes's attempt to lay precisely such a foundation to which Wyeth takes exception here. Dr. Fox's attention was drawn to his testimony in Davis v. Wyeth Laboratories, Inc., 9 Cir. 1968, 399 F.2d 121, and he was given an opportunity to examine the uncertified transcript relied upon by Reyes, out of the sight of the jury and during a luncheon recess. When court reconvened, under questioning by counsel for Reyes, Dr. Fox testified that the transcript, although "somewhat inaccurate" did contain the substance of his prior testimony. He then explained at length why his former statements were in no way inconsistent with his testimony on direct examination here. Wyeth continually objected to this attempt to lay a foundation on the ground that no foundation had been laid. Overruling such objections cannot constitute reversible error.

---

[35] Ray v. Gage, Tex.Civ.App.1954, 269 S.W.2d 411, 419, writ ref.; Robertson v. M/S Sanyo Maru, 5 Cir. 1967, 374 F.2d 463, 465, cert. denied, 1970, 400 U.S. 854, 91 S.Ct. 59, 27 L.Ed.2d 91; Burton v. United States, 5 Cir. 1949, 175 F.2d 960, 965, cert. denied, 338 U.S. 909, 70 S.Ct. 347, 94 L.Ed. 560.

b) The Exclusion of Dr. Nakano's Opinion

Dr. James Nakano, a virologist and the Chief of the Poliovirus Strain Characterization Laboratory in Atlanta, Georgia, was allowed to testify that, based on his analysis of Anita's stool specimens, he had concluded that the etiological agent causing her paralysis was probably a "wild strain". The trial court, however, refused to allow Dr. Nakano, who is not a physician, to advance his opinion as to "the probable cause of Anita Reyes's paralysis". Asserting that this ruling constitutes reversible error, Wyeth points out that another of its experts who is also not a practicing physician was permitted to render an opinion as to the cause of Anita's condition, as were several other experts who based their conclusions on Dr. Nakano's laboratory findings. Aside from indicating that any error in the exclusion of Dr. Nakano's testimony was probably harmless, such arguments have little force. As we concluded in another Texas diversity action:

> Generally, the admission of . . . tendered expert testimony is a matter within the sound discretion of the trial court, and the action of the trial court in admitting or excluding such evidence will be sustained unless clearly and manifestly erroneous.

Scott v. Fancher, 5 Cir. 1966, 369 F.2d 842, 844. It is at least arguable that the effect of a disease virus on a particular human being whom he had not examined was outside of the scope of Dr. Nakano's expertise. In any event, in light of all of the testimony on the issue, the exclusion of his testimony was not so "clearly and manifestly erroneous" as to constitute reversible error.

c) The Admission of Exhibit 13

Wyeth vigorously excepts to the admission into evidence of Plaintiff's Exhibit Number 13, a document purporting to detail the suspected and confirmed cases of polio which occurred in Hidalgo County during 1970, on the ground that counsel for Reyes failed to lay the proper foundation

for admission of the document under the "business records" exception to the hearsay rule.

Exhibit 13 was first referred to during the cross-examination of Mrs. Ruth McDonald, Director of Nursing for the Hidalgo County Health Department. On direct examination, Mrs. McDonald testified that the County Health Department kept statistics and records on communicable diseases and immunization of the population in Hidalgo County and there her "employer" was Dr. Copenhaver, director of the Public Health Unit in Hidalgo and Cameron Counties. On cross-examination she was shown the challenged exhibit, and testified that she had seen the report previously "when it was made up". Mrs. McDonald also identified certain writing on the exhibit as Dr. Copenhaver's handwriting. This tended to link Wyeth with the vaccine given Anita Reyes. The Exhibit was marked "Plaintiff's 13" for identification, but was not offered in evidence.

The following day, Oscar Garza, another defense witness, who is a Health Programs Specialist for the Texas State Department of Health, was confronted with Plaintiff's Exhibit 13 on cross-examination. Exhibit 13 appeared to bear a strong similarity to a list prepared by Mr. Garza, although Mr. Garza's list evidently did not show all of the same entries, and exhibited none of the handwriting previously identified as Dr. Copenhaver's. Mr. Garza demonstrated a general familiarity with the information contained in Exhibit 13, but under interrogation by counsel for Wyeth, he testified that the list was not a record prepared or retained in the regular course of business of *his* office. Exhibit 13 was then offered in evidence by Reyes's counsel, and Wyeth objected on the ground that a proper foundation had not been laid. After a colloquy which revealed that the challenged exhibit had been appended to Dr. Copenhaver's deposition in accordance with a request that he submit all relevant records, the trial court decided

that the record had been sufficiently authenticated to justify admission.

The considerable Texas authority Wyeth marshals to support its position is of little aid, for its assumption that Texas law controls our review of the trial court's decision is erroneous. While state standards may be found to *apply* to evidentiary issues in federal courts, such questions are governed by federal standards in general, and by Fed.R.Civ.P. 43(a) in particular. Bailey v. Kawasaki-Kisen, K. K., 5 Cir. 1972, 455 F.2d 392, 397. Rule 43(a) provides:

> (a) *Form and Admissibility.*
>
> In all trials the testimony of witnesses shall be taken orally in open court, unless otherwise provided by these rules. All evidence shall be admitted which is admissible under the statutes of the United States, or under the rules of evidence heretofore applied in the courts of the United States on the hearing of suits in equity, or under the rules of evidence applied in the courts of general jurisdiction of the state in which the United States court is held. In any case, the statute or rule which favors the reception of the evidence governs and the evidence shall be presented according to the most convenient method prescribed in any of the statutes or rules to which reference is herein made. The competency of a witness to testify shall be determined in like manner.

We are less sanguine than the appellants in assuming that Texas courts would not admit this exhibit as a busness record.[36] We are aware also that it is at least arguably

---

[36] The Texas policy on the admission of business records is embodied in Article 3737e, Vernon's Ann. Texas Civil Statutes (Supp. 1974).

The statute is not specific as to the proof necessary to support a judicial finding that its strictures have been met but at least one decision of the Texas Supreme Court suggests that if the testimony of a "qualified witness" supports an implied finding by the trial judge that the records in dispute were made in the regular course

admissible under the Federal Business Records Act.[37] Yet neither a protracted statutory analysis nor the

---

of business and were made at or reasonably near the time of the recorded act or event, the statutory strictures will have been bridged. See University Savings & Loan Assoc. v. Security Lumber Co., Tex.Sup.Ct.1967, 423 S.W.2d 287, 290.

Here, the testimony of Nurse McDonald supported the court's finding that Exhibit 13 was a business record prepared in the regular course of the business of the Hidalgo County Health Department at or near the time in question. This is particularly true, in that Exhibit 13 was appended by Dr. Copenhaver to his deposition pursuant to a request that he submit copies of all of his records relevant to Anita Reyes's case. In light of the considerable latitude Texas affords the trial judge in admitting evidence, it is by no means clear to us that a Texas appellate court would find the admission of Exhibit 13 to have been erroneous.

[37] The business records exception to the hearsay rule is also addressed by federal statute. Title 28, United States Code, Section 1732(a) in pertinent part provides:

> (a) In any court of the United States and in any court established by Act of Congress, any writing or record, whether in the form of an entry in a book or otherwise, made as a memorandum or record of any act, transaction, occurrence, or event, shall be admissible as evidence of such act, transaction, occurrence, or event, if made in regular course of any business, and if it was the regular course of such business to make such memorandum or record at the time of such act, transaction, occurrence, or event or within a reasonable time thereafter.
>
> All other circumstances of the making of such writing or record, including lack of personal knowledge by the entrant or maker, may be shown to affect its weight, but such circumstances shall not affect its admissibility.

The resemblance of this federal provision to the Texas statute is almost familial and the interpretation given it by the court reveals a certain fraternity as well.

Generally, testimony by the custodian or another qualified witness that the records offered were kept in the regular course of business and that they were prepared at or near the time in issue is a predicate to admission under § 1732(a). See, e.g., United States v. Middlebrooks, 5 Cir. 1970, 431 F.2d 299, 302, cert. denied, 1971, 400 U.S. 1009, 91 S.Ct. 569, 27 L.Ed.2d 622. Yet nowhere does the Act

precarious *Erie* ruminations characteristic of such close cases is necessary to approve the admission of Exhibit 13 here. Rather, Rule 43(a), itself, perceived through the liberal prism of our earlier decisions, furnishes the basis for Exhibit 13's admission. Plainly enough, the Rule is a standard of admission not exclusion; all doubts are to be

---

require that the foundation come from the individual who kept the records or had supervision over them; all that need be established is that the record was kept in the regular course of business. Sabatino v. Curtiss National Bank, 5 Cir. 1969, 415 F.2d 632, 635, cert. denied, 1970, 396 U.S. 1057, 90 S.Ct. 750, 759, 24 L.Ed.2d 752. And, as Judge Thornberry suggests in his able analysis of Section 1732 in *Sabatino*, the determination whether a record has been kept in the regular course of business should be made in light of the purposes of the statute:

> [T]he decisions excluding offered items indicate that the main reason for the statutory language "in regular course of any business" is to provide a check on trustworthiness, in that (1) the records must be kept pursuant to some routine *procedure* designed to assure their accuracy, (2) they must be created for *motives* that would tend to assure accuracy (preparation for litigation, for example, is not such a motive), and (3) they must not themselves be mere cumulations of hearsay or uninformed opinion.

415 F.2d at 637.

Viewed in this way, the summary of suspected and confirmed polio cases in Hidalgo County submitted by Dr. Copenhaver may well have been admissible under the Act. The nature of the report itself and Nurse McDonald's testimony that she had seen the report as it was being compiled at the County Health Department indicate that it was routinely prepared. Obviously the Health Department's motive for accuracy in recording data on so serious an illness would be strong, and the data itself would reflect opinion from sources well-informed. Since the trial court here chose to admit the report once it was satisfied that the record was kept in the regular course of business, that determination can be altered only upon a showing of abuse of discretion. United States v. Middlebrooks, *supra*, 431 F.2d at 392. Were we required to rely upon the Federal Business Records Act, we do not believe that such an abuse would be found.

resolved in favor of admissibility,[38] and even evidence not perceived as admissible when viewed through the receptive trifocals of Rule 43(a), is not necessarily to be excluded.[39] This expansive standard was conceived in Monarch Insurance Co. v. Spach, 5 Cir. 1960, 281 F.2d 401, 411, and born in Dallas County v. Commercial Union Assurance Co., 5 Cir. 1961, 286 F.2d 388, 395, decisions which point the way to our approval of the admission of Exhibit 13 here.

In *Monarch Insurance*, the Court faced the difficulty of interpreting Rule 43(a)'s sanction of evidence admissible "under the rules of evidence heretofore applied in the courts of the United States on the hearing of suits in equity". On its face, this formula might be read as endorsing admission of only that evidence admissible under specific pre-1938 equity precedents. But the notion that in order to admit such evidence the court must pore over ancient volumes in search of pre-Federal Rules dogma was firmly interred, so far as this Court is concerned, by *Monarch Insurance*. Judge, now Chief Judge Brown, writing for the Court, pointed out that the district court sits as a court of equity, and the trial judge is not pinioned to pre-1938 holdings: "his chief censor is the conscience of a Chancellor." Dallas County v. Commercial Union Assurance Co., 286 F.2d at 395.[40] Moreover, not only did

[38] Bailey v. Kawasaki-Kisen, K.K., 5 Cir. 1972, 455 F.2d 392, 397; Household Goods Carriers' Bureau v. Terrell, 5 Cir. 1971, 452 F.2d 152, 160 (en banc); Butler v. Southern Pacific Co., 5 Cir. 1970, 431 F.2d 77, 79, cert. denied, 1971, 401 U.S. 975, 91 S.Ct. 1196, 28 L.Ed.2d 325.

[39] See, e.g., Price v. United States, 5 Cir. 1964, 335 F.2d 671, 677; Dallas County v. Commercial Union Assurance Co., 5 Cir. 1961, 286 F.2d 388, 394.

[40] Moreover, the fact that as an action for damages this suit would not have sounded in equity at common law does not prevent the district judge from admitting Exhibit 13 under the "suits in equity" provision, if equitable principles would have authorized its admission in an equitable action. See, e.g., Treharne v. Calla-

Monarch Insurance greatly expand the scope of evidence admissible within the strictures of Rule 43(a), it also signalled the advent of a still more liberal standard by suggesting that the Rule "does not purport to prohibit the admission of other relevant material probative evidence which, in the considered exercise of judicial wisdom, is trustworthy" 281 F.2d at 411.

The other shoe was dropped a year later in Dallas County v. Commercial Union Assurance Co., when we flatly held that a federal court is not required to cram proffered evidence into one of Rule 43(a)'s pigeonholes in order to find it admissible. Nor must the court find that the exhibit or testimony is within a "readily identifiable and happily tagged" exception to the hearsay rule to admit it. 286 F.2d at 398. Rather, in the words of *Dallas County*, if the exhibit is "necessary and trustworthy, relevant and material", the trial judge is free to exercise his discretion and admit it, so long as he keeps the hearing within reasonable bounds. 286 F.2d at 394, 398; Price v. United States, 5 Cir. 1964, 335 F.2d 671, 677.

From our review of the transcript it is plain that reception of Exhibit 13 posed no threat to the proper conduct of the trial. Neither party contests the exhibit's materiality or relevance; indeed the damage which the appellants allege resulted from its admission establishes those characteristics beyond any doubt. Since Exhibit 13 was "necessary and trustworthy", it was properly admitted under the liberal *Dallas County* standard.

Supporting this conclusion are several post-*Dallas County* decisions by this Court. In Butler v. Southern Pacific Co., 5 Cir. 1970, 431 F.2d 77, 80, cert. denied, 1970, 401 U.S. 975, 91 S.Ct. 1196, 28 L.Ed.2d 325, a proffered report was held to be necessary because information in it went "to the

---

han, 3 Cir. 1970, 426 F.2d 58, 62-63; Hope v. Hearst Consolidated Publications, Inc., 2 Cir. 1961, 294 F.2d 681, 688-690, cert. denied, 1902, 368 U.S. 956, 82 S.Ct. 399, 7 L.Ed.2d 388; 9 C. Wright & A. Miller, Federal Practice and Procedure, § 2403 at 317 n. 39.

heart of the case" and it was trustworthy because it was in the "direct financial interest" of the maker of the report to prepare it accurately. In the other instance, Sabatino v. Curtiss National Bank, 5 Cir. 1969, 415 F.2d 632, 636, cert. denied, 1970, 396 U.S. 1057, 90 S.Ct. 750, 759, 24 L.Ed.2d 752, trustworthiness was revealed both by the financial interest of the keeper of the record in its accuracy, and the fact that it "was kept according to a regular procedure of entries made contemporaneously with the events it recorded". There was no question of necessity; the sponsoring witness was dead.

So analyzed, the report at issue here was properly admitted. The report of suspected and confirmed polio cases, inscribed with the word "Wyeth," was crucial in linking Wyeth to the vaccine which allegedly caused Anita Reyes's polio. Although it does not appear from the record why Dr. Copenhaver did not testify at trial, we do not believe that Reyes was required to demonstrate his unavailability in order to meet the necessity test. Cf. Butler v. Southern Pacific Co., 431 F.2d at 80. There were also sufficient indicia of trustworthiness to justify admission. Nurse McDonald testified that she had witnessed the report's preparation, and that it was laden with Dr. Copenhaver's handwriting. The motivation for accuracy in a record prepared by a public health official concerning outbreaks of serious disease within an area committed to his charge is obvious. A brand of expertise sufficient to insure accuracy may be assumed; there can be no suggestion that in analyzing poliomyelitis cases Hidalgo County Public Health officials were amateurish or careless. The notation as to the origin of the lot number of the vaccine ingested by Anita Reyes shares this reasonable presumption of accuracy. Exhibit 13, necessary and trustworthy, met this Court's strictures for admission.

(d) The Sufficiency of the Evidence

Finally, we confront the appellant's contentions that the trial court erred in denying its motions for a directed ver-

dict, for judgment notwithstanding the verdict, and for a new trial. One argument urged by Wyeth in support of this conclusion—that there was no evidence that Wyeth had a duty to warn Anita Reyes—we discussed in dealing with the substantive law. Thus here we need consider only the contentions that the evidence was insufficient to support the verdict and judgment, that the verdict was the result of passion and prejudice, and that it was against the clear weight of the evidence.

The yardstick against which such motions must be measured is a federal one:

> On motions for directed verdict and for judgment notwithstanding the verdict the Court should consider all of the evidence—not just that evidence that supports the non-mover's case—but in the light and with all reasonable inferences most favorable to the party opposed to the motion. If the facts and inferences point so strongly and overwhelmingly in favor of one party that the Court believes that reasonable men could not arrive at a contrary verdict, granting of the motions is proper. On the other hand, if there is substantial evidence opposed to the motions, that is, evidence of such quality and weight that reasonable and fair-minded men in the exercise of impartial judgment might reach different conclusions, the motions should be denied, and the case submitted to the jury.

Boeing Co. v. Shipman, 5 Cir. 1969, 411 F.2d 365, 374. As an appellate court, our sole function is to ascertain whether there is a rational basis in the record for the jury's verdict; we are forbidden to usurp the function of the jury by weighing the conflicting evidence and inferences and then reaching our own conclusion.[41]

There was conflicting testimony as to the cause of Anita Reyes's polio. In answer to a special interrogatory, the

---

[41] Borel v. Fibreboard Paper Co., *supra* note 5, 493 F.2d at 1092; Helene Curtis Industries, Inc. v. Pruitt, *supra* note 12, 385 F.2d at 850.

jury found, despite the testimony of Wyeth's expert witnesses to the contrary, that Anita's polio was vaccine-induced. Essentially Wyeth complains that the jury credited the testimony of the physician who treated Anita Reyes rather than evidence offered by its parade of experts. Presented with conflicting credible evidence, such a determination was within the jury's prerogative; expert witnesses appear to assist in the court's decision-making process, not to control it. Houston Natural Gas Corp. v. Pearce, Tex.Civ.App.1958, 311 S.W.2d 899, 909, writ ref. n. r. e.; see Steakley, Expert Medical Testimony in Texas, 1 St. Mary's L.J. 161-162 (1969). The rule is the same in the Fifth Circuit. See Alman Brothers Farm & Seed Mill, Inc. v. Diamond Laboratories, Inc., 5 Cir. 1971, 437 F.2d 1295, 1298. The evidence for Wyeth was somewhat persuasive; there is no doubt about it. The evidence for Reyes was substantial and at least as persuasive, looking at the record coldly. Consequently, the trial court was guilty of no error in denying Wyeth's motions for a directed verdict and judgment n. o. v. Denial of a motion for a new trial will be reversed only upon showing of clear abuse of discretion by the trial court, Davis v. Yellow Cab Co., 5 Cir. 1955, 220 F.2d 790, 791. In light of the conflicting evidence, the denial of the motion reveals no abuse here.

IV.

Finally, we come to a series of contentions under the general heading of challenges to comments, instructions, and charges by the trial judge. Some of these have already been considered. Remaining are Wyeth's objections to specific instructions by the trial court, particularly: (1) its definition of the term "epidemic," (2) its failure to define "medically cognizable risk," and (3) its failure to instruct the jury as to the issue of "relative risk".

Federal courts apply their own rules[42] in the manner and method of charging the jury. Where state rights are involved, state law must, of course, be looked to for the substance of the instructions, but the form of the charges and the language employed to convey the substance are procedural, hence federal, concerns. See 9 C. Wright & A. Miller, Federal Practice and Procedure, § 2255 at 651 (1971). Where as here, the issues are submitted upon a general verdict to be accompanied by answers to specific interrogatories, the Federal Rules provide simply that, "[t]he court shall give such explanation or instruction as may be necessary to enable the jury to make answers to the interrogations and to render a general verdict. . . ."[43] Not surprisingly, then, while a litigant is entitled to have the trial judge advise the jury of his theories and claims (to the extent they are supported by the evidence adduced at trial), the actual form of the instructions is within the trial court's discretion. Counsel cannot, therefore, require that an instruction be rendered in the categorical language that he fancies would be most beneficial to his cause.[44]

To requests for use of specific verbal formulae, definitions, or synonyms a rule of reason should apply. Unadorned language comprehensible to the average juror, not legal jargon, should characterize the instructions. Words familiar to persons of average intelligence do not require definition.[45] In reviewing the linguistic choices

---

[42] Barrett v. Virginian Ry. Co., 1919, 250 U.S. 473, 39 S.Ct. 540, 63 L.Ed. 1092; Nudd v. Burrows, 1875, 91 U.S. 426, 23 L.Ed. 286.

[43] See note 27 *supra*.

[44] Delancey v. Motichek Towing Service, Inc., 5 Cir. 1970, 427 F.2d 897, 902; Kayo Oil Co. v. Sammons, 5 Cir. 1963, 321 F.2d 729, 730.

[45] See McClendon v. Reynolds Electrical & Engineering, 5 Cir. 1970, 432 F.2d 320, 323; Government Employees' Insurance Co. v. Davis, 5 Cir. 1959, 266 F.2d 760, 765; 9 C. Wright & A. Miller, *supra*, § 2556 at 657-58.

made by the trial court, the charge must be read as a whole. An ambiguous phrase or inaccurate clause does not necessarily destroy an entire instruction. Delancey v. Motichek Towing Service, Inc., 5 Cir. 1970, 427 F.2d 897, 901. Rather, the test is whether the charge, viewed as a whole, was sufficiently clear and accurate to be understood by jurors of ordinary intelligence, and to be applied by them to the evidence so as to reach a proper conclusion. [46]

Wyeth's objections to the instructions here do not present serious difficulties. The appellant first contends that the issue whether there was a polio epidemic in the Rio Grande Valley at the time Anita Reyes contracted the disease should never have been presented to the jury, and, alternatively, that the trial judge's definition of the term "epidemic" was erroneous. It is manifest that both arguments center on the definitional dispute. Wyeth produced eight expert medical and epidemiological witnesses, each of whom testified that in his opinion a polio epidemic existed in Hidalgo County, Texas in May 1970. To arrive at this conclusion, Wyeth's experts employed an "epidemiological definition" of epidemic, according to which two cases within a given city, county, or metropolitan area in a four week period may constitute a polio epidemic. [47] Dr. Ramiro R. Casso, the Hidalgo County general practitioner who testified as Reyes's medical expert, referred to a medical dictionary to define "epidemic" as "[disease] attacking many

---

[46] Rivers v. Angf. A/B Tirfing, 5 Cir. 1971, 450 F.2d 12, 15; McGuire v. Davis, 5 Cir. 1971, 437 F.2d 570, 574.

[47] This definition, which appeared as part of the 1969 Recommendations of the United States Public Health Service's Advisory Committee on Immunization Practice, is as follows: "An 'epidemic' of poliomyelitis is defined as two or more cases caused by the same polio virus type and occurring within a four-week period in a circumscribed population such as that of a city, county or metropolitan area."

people in any region at the same time".[48] From a review of its comments during the trial it is apparent that the court, properly, did not consider itself bound by either definition,[49] although in its instructions to the jury the court employed a definition not unlike that read from the medical dictionary by Dr. Casso.[50]

Here the question whether there was an epidemic in Hidalgo County during the relevant period bore directly on an ultimate issue of fact. Did Anita Reyes contract polio from a wild virus strain or from the defendant's vac-

---

[48] This definition was the first, of three, appearing in Dorlan's Illustrated Medical Dictionary, Twenty-Fourth Edition, which Dr. Casso testified was "the most generally accepted dictionary by medical people."

[49] For example, at the precharge deliberations, the court observed:

> You see, I don't think we are bound by what these doctors say, or the government says, or what anybody says about the fact what an epidemic is.

But see footnote 50.

[50] The court instructed:

> Now we are talking about epidemic and we have heard lots of testimony here about two cases within thirty days or four cases within thirty days, and all these doctors have testified to that. Some of them say for operational purposes. Well, that's the evidence you can take into consideration on whether or not there was any epidemic in the area. But for our purpose here I am going to tell you that under the law that the term epidemic is a relative term, and the question of how many cases constitute an epidemic is a question of fact depending upon the prevailing circumstances. The term epidemic in its common and ordinary meaning applies to any disease which is widely spread or generally prevailing at a given place and time. That is what an epidemic is. You will be guided by that definition.
>
> Now if you find that there was an epidemic and that this girl got her paralytic polio from the wild virus as the defendant would let us view the evidence, because of the report of Dr. Nakano that there is probably a wild virus, then you have to say by your verdict she did not contract the paralytic polio as a result of having taken the defendant's vaccine.

cine? In light of its importance, the trial judge submitted the "epidemic" issue to the jurors; they had heard the conflicting testimony. He defined "epidemic" in terms pertinent to determining the question of causation. He declined to use Wyeth's "epidemiological definition", a definition that might have confused the jurors. He did not abuse his discretion in doing so. The substance of the charge was correct, and the appellants were not entitled to an instruction in the specific terms they desired.

Wyeth objected to the trial court's failure to define the term "medically cognizable risk" used in Interrogatories Nos. 3 and 4 and its failure to charge the jury on the issue of "relative risk". Wyeth insists that a definition of "medically cognizable risk" was necessary to insure that the jury would realize that there had to exist some danger or risk from the vaccine in order to conclude that Wyeth had a duty to warn.

Yet whatever the form of the interrogatories, the link between "medically cognizable risk" and "duty to warn" was made clear by the court's instructions.[51] It appears

---

[51] In explaining the interrogatories to the jury the court instructed:

> Now if you find that she did get the polio from this vaccine and not from a wild virus, then I must ask you do you find from a preponderance of the evidence that on May 8, 1970, there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking trivalent oral vaccine. We have to view this as of May 8th, at that time. Did Wyeth know that this trivalent oral vaccine that they were selling to the State of Texas to immunize children was unavoidably dangerous—I mean unreasonably dangerous or unavoidably unsafe, and should they have advised the parents of Anita of this risk? Did they know that their product was unreasonably dangerous or unavoidably unsafe to be given in the southern tier of states between the months of April and November or March and November, I mean? Did they know that? And if they knew it or should have known it, did they give them warning, to the consumer? And in that connection I tell you that the law is that if you find that the product was unreasonably

to us that the challenged interrogatories were neither confusing nor misleading:

"INTERROGATORY NO. 3

"Do you find from a preponderance of the evidence that on May 8, 1970, there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking trivalent oral vaccine?

"The jury will answer 'there was a risk' or 'there was not a risk'."

"INTERROGATORY NO. 4

"Do you find from a preponderance of the evidence that there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking the vaccine after March 31st, and before November 1, 1970?

"The jury will answer 'there was a risk' or 'there was not a risk'."

The terms [sic] "medically cognizable risk" is self-defining, clear, and comprehensive to men of average intelligence; it need not be belabored in jury instructions. Use of these interrogatories did not prejudice Wyeth's presentation of its case.

---

dangerous or unavoidably unsafe, and that such condition was known to the defendant, or in the exercise of reasonable care should have been known to the defendant, the law imposes upon them a duty to use reasonable methods to inform the consumer of the nature of the product so that the consumer may evaluate whether or not he should use the product and take the risk.

The court later added:

Now they say, the way I understand it from their evidence here, that these people have failed to prove that this product was unreasonably dangerous or unavoidably unsafe, that the records show that the vaccine has worked in thousands and thousands of cases. On May 8th they didn't think there was any risk of any kind, then they had no duty—or could not find out if there was a risk—then they had no duty to warn because if I don't know of a risk how can I warn anybody? I have to know of a risk in order to have a duty to warn. So I either know about it or I should have known about it.

Wyeth contends that the trial court should have instructed the jury to consider the "relative risk" of contracting polio from the vaccine as opposed to contraction from a natural source. This, Wyeth argues, would have presented the question more fairly than did the charge on "medically cognizable risk", for the jury would have weighed the probabilities that Anita Reyes was paralyzed by vaccine-induced rather than "wild" polio virus. Yet this is precisely the consideration invited by Interrogatories 3 and 4. The distinction, therefore, is verbalistic rather than substantial and to have refused to charge in the words Wyeth preferred constitutes no error.

In two lengthy sections of its brief, Wyeth attacks the trial court's summary of the evidence in the course of instructing the jury and cites as prejudicial various comments advanced by the court during the trial. More specifically, Wyeth excepts to the court's comments on the evidence in explaining the first two interrogatories to the jury,[52] and the court's discussion of the preponderance of

---

[52] Compare interrogatories 1 and 2. In his summary of evidence relevant to the first interrogatory, the trial judge made reference to the testimony of Dr. Louis Miller, a physician in the employ of the United States Public Health Service whose testimony tended to demonstrate that it was only Wyeth's vaccine that was available at the Mission clinic on May 8, 1970, the day Anita Reyes received her vaccine. Wyeth urges that since specific reference was not made to the testimony of three witnesses whose recollections cast doubt on Dr. Miller's conclusion, it was prejudiced by this summary. Aside from our conclusion in the text that the trial court fairly summarized the evidence and specifically left the factual decisions for the jury, it might be observed that the testimony Wyeth relies upon does not appear to be probative of a conclusion contrary to that reached by Dr. Miller.

Nor is the appellant's objection to the court's summary of evidence relevant to the second interrogatory meritorious. Essentially, Wyeth seeks to reargue the court's failure to employ its epidemiological definition of "epidemic" in the charge and summary. We have discussed that contention earlier in the opinion.

the evidence standard.[53] Wyeth asserts that in each instance the court's summary of the evidence unfairly emphasized Reyes's theory of the case at the expense of its own. We disagree with Wyeth's assertion. Federal trial courts have a proper discretion in summarizing and commenting upon the evidence in an effort to expedite the jury's determination of factual issues. See, e. g., Trezza v. Dame, 5 Cir. 1967, 370 F.2d 1006, 1008-1009. Indeed, explanatory comments are prejudicial only when the court fails to make clear to the jurors that they alone have the burden of decision. See Stuckey v. Andrews, 5 Cir. 1957, 249 F.2d 828; 11 C. Wright & A. Miller, supra, § 2886 at 292-294 and n. 73. Here the trial court went to great lengths to impress upon the jurors that they were the exclusive arbiters of

---

[53] The "preponderance of the evidence" instruction rendered by the court was scarcely novel, yet Wyeth contends that it was prejudiced by the court's admonition that the jury ought not be influenced by the number of witnesses produced by either party. The court instructed:

> Preponderance of the evidence also means that it is the evidence that you believe believable. Doesn't depend on numbers of witnesses because ten people can sit up here and tell you that the horse he saw was black, and one man can come up here and testify that the horse he saw was white. And if you believe the man that says it was white then you can disregard the ten that said it was black, see, if the reasons he gives for telling you the horse is white seem more plausible to you, see, or preponderates. So the number of witnesses has nothing to do with this. It is the quality of the evidence and the reasons for the evidence that count. So that is another way of telling you what preponderance of the evidence means.

This segment of the court's charge was error, Wyeth asserts, in that it abraded the impact of Wyeth's extensive expert testimony. To the contrary, we find that offered in the midst of a lengthy and accurate charge explaining preponderance, such an explanation is laudable to the extent that it tends to concentrate the vision of the jury on the preponderance of *believable* evidence rather than the numerical superiority of witnesses or exhibits. It certainly was not error.

the facts, the sole judges of the witnesses' credibility.[54] Since we also conclude that the summaries and comments upon the evidence were basically fair, we find no ground for reversal here.

Finally, Wyeth contends, in an argument bolstered by twenty-three detailed references to the trial transcript, that the cumulative effect of the trial court's comments on the evidence and sympathetic references to Anita Reyes so prejudiced its case as to require reversal. We shall not attempt to consider the challenged comments separately. We have examined the transcript from beginning to end. We have paid particular attention to the court's instruction to the jury. We hold that the court's comments were generally designed to fulfill its responsibility to keep the trial progressing on course and at a proper pace. A trial judge takes no vow of silence; he vows to follows the law, to be fair, and to serve as an arbiter in the interests of justice. See Nordmann v. National Hotel Co., 5 Cir. 1970, 425 F.2d 1103, 1109. We consider that the trial judge conducted a fair trial. Nevertheless, we do not approve of the trial judge's over-frequent references to Anita Reyes as "this little girl". It was obvious to all that Anita was a little girl. And she was the victim of a great tragedy. But judges must steel themselves to avoid any comment that a jury might construe as bias in favor of any "little girl", or

---

[54] The court admonished at the outset of its charge:

> Now you are the exclusive judges of the facts and the credibility of the witnesses and the weight to be given to their testimony. But the law you must take from me for it would be a violation of your sworn duty as jurors to take any other view of the law other than that as I give it to you.
>
> Now during the trial of this case it has been necessary for me to make rulings on objections. I have also asked some witnesses questions, and during the conduct of this trial if you have gotten any ideas that I am leaning one way or another in this case I want you to dispel that from your mind because that was not my intention. I am very happy to have you decide the facts in the case and relieve me of that responsibility.

any injured claimant. Here, a thorough examination of the transcript, consideration of the trial judge's rectitude throughout the trial, and the trial judge's curative instruction [55] to the jury convince us that his references to Anita as "this little girl" were not so harmful to Wyeth's cause as to constitute reversible error.

V.

In closing, we feel that we should comment on the important policy considerations raised in the briefs of the amici curiae, the American Academy of Pediatrics [AAP] and the Conference of State and Territorial Epidemiologists [CSTE]. Both insist that the holding we reached is "dangerous" to the nation's preventive medicine programs and contravenes a strong public policy favoring large-scale participation in immunization efforts to combat infectious disease. The crucial points of the argument are two: first, that any effort to warn vaccinees will be futile and frightening, leading only to confusion, and second, that a warning is unnecessary once epidemiologists have reached a deliberate medical judgment that universal vaccination is necessary. These public health policy questions cut across the law. We realize their importance.

Citing a recent Texas statute which requires that all Texas schoolchildren receive polio vaccine, [56] the AAP insists that this renders any warnings futile. This argument assumes, of course, that the only options available are to ingest the oral vaccine at the clinic or to eschew immunity. Obviously, however, one can choose to be innoculated with killed-virus Salk vaccine, either to provide complete immunity or as a precautionary prelude to ingesting oral vaccine. The AAP also insists that the warnings would be so complex or misleading as to confuse and frighten potential vaccinees. This is possible. Yet we believe that a warning

[55] See note 54, *supra*.

[56] 67 Tex.Stat.Rev. § 209(a) (1971).

advising a patron of a public health clinic of the relative risk of contracting polio from a "wild" source against the slight chance of contracting it from the vaccine would not be terrifying or confusing. Some would be sufficiently concerned to take the Salk vaccine innoculation. Others, perhaps those who, like the plaintiff in *Davis*, have as great a chance of contracting polio from the vaccine as contracting it from a wild source, will undoubtedly be deterred from immunization. The AAP's answer to this problem is to warn no one. That is no answer.

This position raises a policy consideration scarcely less urgent than the need for mass immunization from disease; the right of the individual to choose and control what risk he will take, in the absence of an individualized medical judgment by a physician familiar with his needs and susceptibilities. Recognition of this right counters the argument advanced in the CSTE's brief that once an epidemiological balancing of the risks of immunization has been made, no warning is required. Clearly, the rationale excusing warnings to ultimate consumers of prescription drugs whose physicians have balanced the risk for them, cannot be extended to a medical determination that statistical probabilities justify universal immunization. In such cases, the test is that outlined in *Davis:*

> When . . . the risk qualitatively (e. g., death or major disability) as well as quantitatively, on balance with the end sought to be achieved, is such as to call for a true choice judgment, medical or personal, the warning must be given.

399 F.2d at 129-130. Here the qualitative risk was great, the quantitative risk minute. The end sought to be achieved —immunization—is important both to the individual and society. Striking the balance in this case is difficult, but by adding two elements to the *Davis* calculus we conclude that a sufficient "true choice judgment" was involved here to lend strong policy support to our holding. First, the risk

here was foreseeable statistically, although unknowable individually. Thus, unlike the abreaction cases, here there was a basis for rational choice. Second, a choice here, if given, had an opportunity to be efficacious, since reasonable alternatives to taking the oral vaccine were available. Therefore, the choice was not so clear cut that even offering the opportunity to choose was meaningless.

Moreover, there is a third policy factor at work here overlooked by the amici:

> Until Americans have a comprehensive scheme of social insurance, courts must resolve by a balancing process the head-on collison between the need for adequate recovery and viable enterprises. . . . This balancing task should be approached with a realization that the basic consideration involves a determination of the most just *allocation of the risk of loss* between the members of the marketing chain.

Helene Curtis Industries, Inc. v. Pruitt, *supra*, 385 F.2d at 862. Statistically predictable as are these rare cases of vaccine-induced polio, a strong argument can be advanced that the loss ought not lie where it falls (on the victim), but should be borne by the manufacturer as a foreseeable cost of doing business, and passed on to the public in the form of price increases to his customers.[57]

---

[57] See, e. g., Calabresi & Bass, Right Approach, Wrong Implications: A Critique of McKean on Products Liability, 38 U.Chi.L. Rev. 74 (1970); Calabresi, Some Thoughts on Risk Distribution and the Law of Torts, 70 Yale L.J. 499 (1961); Morris Enterprise Liability and the Actuarial Process—The Insignificance of Foresight, 70 Yale L.J. 554 (1961); 46 N.Y.U.L.Rev. 403 (1971); see also Escola v. Coca Cola Bottling Co., Cal.Sup.1944, 24 Cal.2d 453, 150 P.2d 436, 440 (Traynor, J., concurring). It can also be argued, of course, that since all society benefits from universal immunization against infectious disease, the loss should be borne by the local, state or federal government. Unless the doctrine of sovereign immunity is significantly altered, however, such a loss distribution scheme does not appear to be likely. See Merrill, Compensation for Prescription Drug Injuries, 59 Va.L.Rev. 1, 102 (1973).

Contrary to the assertions of the AAP and the CSTE, we feel strongly that our holding is in accord with public policy considerations. We recognize both the essential role the city health clinic and the rural county clinic play in the nation's public health scheme, and the dangers that their depersonalized medical treatment pose.[58] We do not then, lay down an absolute duty to warn all who receive medication at public clinics. Instead, we hold that in the case of a prescription drug which is unavoidably unsafe, and as to which there is a certain, though small, risk throughout the population, there must be *either* a warning—meaningful and complete so as to be understood by the recipient—*or* an individualized medical judgment that this treatment or medication is necessary and desirable for this patient. Anita's parents received neither. Wyeth is therefore liable for the consequence of its failure to market its unavoidably unsafe product in such a way as to warn Anita's parents of its unreasonably dangerous condition.

The judgment is affirmed.

APPENDIX A: INTERROGATORIES

The interrogatories submitted to the jury and the jury's answers are as follows:

INTERROGATORY NO. 1

Do you find from a preponderance of the evidence that Anita Reyes received a polio vaccine from Defendant Wyeth's Lot No. 15509?

The Jury will answer "She did" or "She did not".

We, the Jury, answer: She did.

---

[58] See 56 Geo.L.J. 1016 (1968); 5 San Diego L.Rev. 422 (1968).

INTERROGATORY NO. 2

Do you find from a preponderance of the evidence that Anita Reyes contracted paralytic polio as a result of having taken Defendant's vaccine?

The Jury will answer "She did" or "She did not".

We, the Jury, answer: She did.

If you answered this "She did not", then you need not answer any other issue.

INTERROGATORY NO. 3

Do you find from a preponderance of the evidence that on May 8, 1970, there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking Trivalent Oral Vaccine?

The Jury will answer "There was a risk" or "There was not a risk".

We, the Jury, answer: There was a risk.

INTERROGATORY NO. 4

Do you find from a preponderance of the evidence that there was a medically cognizable risk that Anita Reyes might contract paralytic polio by taking the vaccine after March 31st, and before November 1, 1970?

The Jury will answer "There was a risk" or "There was not a risk".

We, the Jury, answer: There was a risk.

If you have answered either or both interrogatories No. 3 and 4 "There was a risk", then you will answer the following Interrogatory.

INTERROGATORY NO. 5

Do you find from a preponderance of the evidence that the Defendant Wyeth failed to warn the parents of Anita Reyes of the risk that you have found so that they could make their choice?

The Jury will answer "They failed" or "They did not fail".

We, the Jury, answer; They failed.

INTERROGATORY NO. 6

What sum of money, if paid now in cash, would compensate Anita Reyes for the injuries sustained by her?

The Jury will answer in dollars and cents.

We, the Jury, answer: $200,000.00.

APPENDIX B: POLIOMYELITIS

It was not until about 1950 that scientists and physicians really began to understand how poliomyelitis attacks its victims. They learned that polio is caused by an enterovirus which grows in the intestinal tract, but that the virus is introduced into the body orally, through the mouth. After entering the body, the virus reproduces rapidly in the alimentary tract, and when it reaches the lower intestinal tract its growth causes what could be termed an "infection". This does not mean that the individual "infected" has contracted polio; upwards of 80 percent of the population is naturally immune to polio virus, and only about one of every hundred persons who experience the intestinal viral infection will later manifest clinical symptoms of polio. When disease does result, medical scientists believe, the virus moves, perhaps through the bloodstream, from the intestinal tract or alimentary tract to the spinal column, where it attacks the anterior horn cells, the "grey matter"

within the spinal column. Destruction of sufficient "grey matter" will result in "motor neuron disease", that is, muscular paralysis.

The initial problem facing researchers attempting to develop a vaccine—cultivation of a growth of polio virus in tissue outside the body—was solved by Dr. Enders at Harvard University in 1949. The scientists also learned that polio virus was of three distinct types, and that to provide effective protection, a vaccine would have to immunize the vaccinee to all three types.[59] The first breakthrough resulted from the research of Dr. Jonas Salk, who perfected a "killed virus" vaccine to be administered by innoculation. To produce this vaccine, polio virus is grown in a tissue culture and clinically "killed", that is, rendered incapable of causing disease. In killing the virus, however, no chemical alteration occurs and when it is introduced into the body in the vaccine, the virus acts as an antigen to prompt the production of antibodies. Should a wild or virulent strain of polio virus enter the bloodstream, the antibodies generated as a reaction to the vaccine will destroy it, and the vaccinee will avoid polio.

In 1955 after extensive tests were conducted under the auspices of The National Foundation for Infantile Paralysis (March of Dimes) the researchers concluded that the Salk vaccine was effective and, if the virus were killed, completely safe.[60] The Salk vaccine then became the primary

---

[59] These are commonly referred to as Type I, Type II and Type III, respectively. To the extent that the differences among the three types are relevant, they are referred to in the text. It is undisputed, however, that Anita Reyes suffers from Type I polio.

[60] When Salk vaccine which inadvertently contained some unkilled virulent viral strains was released for use, however, as in the "Cutter incident" of 1955, several cases of vaccine-induced polioymelitis resulted. See, Gottsdanker v. Cutter Laboratories, Cal.App.1960, 182 Cal.App.2d 602, 6 Cal.Rptr. 320.

weapon against polio. But the killed virus vaccine nonetheless exhibited several drawbacks. It had to be injected by hypodermic needle, and a separate innoculation was required for each type of polio virus, as were repeated "booster" injections. Most importantly, perhaps, the Salk vaccine failed to immunize the intestinal tract of the vaccinee. Thus, individuals themselves immunized could still pass the virus to non-immune persons with whom they came in contact. These limitations led to efforts to produce a completely effective oral vaccine, the most successful of which was that of Dr. Albert Sabin. Developed in the middle and late 1950's, the Sabin oral vaccine introduced living but attenuated polio virus into the recipient's system. An attenuated polio virus is one which laboratory processes have rendered incapable of producing disease (to the extent of attenuation), but which retains sufficient strength to cause the production of antibodies to resist and destroy an attacking wild or virulent polio virus in the vaccinee's alimentary tract. Three types of "monovalent" vaccines were developed, one to deal with each type of polio virus, but through a "titering" or mixing process, a single "trivalent" oral vaccine can be produced which, upon ingestion, will provide protection against all three types of virus.

Like its "killed virus" predecessor, the Sabin vaccine was extensively tested worldwide to determine whether it was safe and effective for general use. When favorable results were achieved, the vaccine was licensed for manufacture and sale in the United States by the Division of Biologic Standards of the National Institute of Health [D.B.S.], an arm of the Department of Health, Education and Welfare. Wyeth Laboratories was among the three original licensees who were authorized to prepare and distribute the vaccine only as a prescription drug. Irrespective of which licensee prepares the vaccine, it is derived from a common source: a seed virus obtained from Dr. Sabin. The "seed virus" from which Wyeth Laboratories

vaccine is produced was obtained from Dr. Sabin by Pfizer, Ltd., of England, and is repeatedly reproduced by them in a culture of monkey tissue. Reproduction is rapid, and the virus is frequently "harvested" and the vaccine prepared in separate "lots". At this point Pfizer conducts extensive tests on each lot to ensure that it is safe and effective. Once satisfied by its laboratory findings, Pfizer ships the lot of vaccine to the D.B.S., where it is again subjected to rigorous testing.[61] If the vaccine meets D.B.S. standards, it is released to the manufacturing laboratory, where the vaccine is titered or mixed.

Despite careful preparation and testing, it is apparent that live virus oral polio vaccine cannot be stripped of all danger. As early as January 1961, a subcommittee of a Health, Education and Welfare Department Committee on Poliomyelitis Control expressed concern about the "known potentiality of reversion to virulence of live poliovirus vaccine." A year and one-half later, both a subcommittee of the Association of State and Territorial Health Officers and the Surgeon General's own Special Advisory Committee on Oral Poliomyelitis Vaccine, concluded that, at least where Type III oral vaccine was concerned, a causal connection exists between administration of the vaccine and the occurrence of poliomyelitis in some adults. Thus a "small but definite risk" attaches in feeding Type III oral vaccine to adults.[62] By July 1964, with more data available, the Surgeon General's Special Committee found that 15 cases of polio deemed *compatible* with vaccine causation had followed ingestion of Type I vaccine, 2 had followed ingestion of Type II, and 36 had followed ingestion of Type III. The Committee concluded that "at least some

[61] A more extensive discussion of the nature and complexity of the tests may be found in Griffin v. United States, E.D.Pa.1972, 351 F.Supp. 10.

[62] See Davis v. Wyeth Laboratories, 9 Cir. 1969, 399 F.2d 121, 123-125.

of these cases were caused by the vaccine".[63] This is not to say that the Special Committee concluded that these cases *were* produced by the vaccine; to the contrary, the members cautioned that "no laboratory tests available can provide a definitive answer". Rather, they employed a brief catalogue of symptoms[64] which they believed would separate those cases compatible with vaccine-causation from those clearly caused by wild strains, and would further separate the "probable" vaccine-related cases from those merely possibly associated with it.[65]

---

[63] Report of the Special Advisory Committee on Oral Poliomyelitis Vaccine to the Surgeon General, Public Health Service, 1964 at 4. A report by the Health, Education and Welfare Department's Center for Disease Control indicates that for the year 1964, 20 of 56 reported cases could be associated with vaccine ingestion. Center for Disease Control, [Department of Health, Education and Welfare], 1964 Surveillance Report, at 3.

[64] As paraphrased in Reyes' brief, these symptoms include:

1. An onset of illness between 4 and 30 days following feeding of the specific vaccine type in question and with[sic] an onset of paralysis not sooner than six days after the feeding.
2. Significant residual lower-motor-neuron paralysis.
3. Laboratory data not inconsistent with respect to multiplication of the vaccine virus fed.
4. No evidence of upper motor neuron disease, definite sensory loss, or progression or recurrence of paralytic illness one month or more after onset.

These compatible cases were further subdivided into "probable" and "possible" cases employing the following guidelines for "probable" cases:

1. Evidence of fever at onset of paralysis.
2. History of systemic illness preceding the development of paralysis.
3. Clinical evidence of meningeal involvement manifested either by nuchal rigidity or cerebrospinal fluid cell count greater than 10 cells per cubic milliliter.

[65] For a further discussion of the development of polio vaccine, and the elaborate testing procedures, see, e.g., Davis v. Wyeth Laboratories, Inc., 9 Cir. 1969, 399 F.2d 121; Griffin v. United States, E.D.Pa.1972, 351 F.Supp. 10; Stahlheber v. American Cyanamid Co., Mo.Sup.Ct.1970, 451 S.W.2d 48.

APPENDIX B

VERNON'S EDUCATION CODE OF TEXAS

§ 2.09. Immunization

(a) No person may be admitted to any elementary or secondary school or institution of higher education unless he has been immunized against diphtheria, rubeola, rubella, tetanus, poliomyelitis, and smallpox, except as provided in Subsection (c).

(b) Subject to the provisions of Subsection (c) the State Board of Health may modify or delete any of the immunizations in Subsection (a) or may require immunizations against additional diseases as a requirement for admission to any elementary or secondary school or institution of higher education.

(c) No form of immunization is required for a person's admission to any elementary or secondary school or institution of higher education when the person applying for admission submits to the admitting official either of the following:

(1) an affidavit signed by a doctor who is duly registered and licensed under the Medical Practice Act of Texas, in which it is stated that, in the doctor's opinion, the immunization required would be injurious to the health and well-being of the applicant or any member of his family or household; or

(2) an affidavit signed by the applicant or, if a minor, by his parent or guardian stating that the immunization conflicts with the tenets and practice of a recognized church or religious denomination of which the applicant is an adherent or member; provided, however, that this exemption does not apply in times of emergency or epidemic declared by the Commissioner of Health.

(d) The State Department of Health shall provide the required immunizations to children in areas where no local provision exists to provide these services.

(e) A person may be provisionally admitted to an elementary or secondary school or institution of higher education if he has begun the required immunizations and if he continues to receive the necessary immunizations as rapidly as is medically feasible. The State Department of Health shall promulgate rules and regulations relating to the provisional admission of persons to an elementary or secondary school or institution of higher education.

Amended by Acts 1971, 62nd Leg., p. 702, ch. 67, § 1, eff. April 26, 1971; Subsec. (b) amended by Acts 1971, 62nd Leg., p. 1443, ch. 398, § 1, eff. May 26, 1971; Subsec. (e) added by Acts 1971, 62nd Leg., p. 1441, ch. 393, § 2, eff. May 26, 1971.

APPENDIX C

PRESIDENTIAL DOCUMENTS

Title 3—The President

PROCLAMATION 4329

Immunization Action Week, 1974

By the President of the United States of America

A Proclamation

This Nation has always been committed to fostering the health of its people, and particularly of its children. Immunization against disease has been an exciting chapter in that effort. The United States can take pride in the dedicated research which has produced safe and effective vaccines against polio, measles, rubella, and other childhood diseases.

Cooperation by the medical profession and public health organizations in distributing these vaccines to children has achieved dramatic reductions in diseases which can kill, cripple, or cause birth defects, including mental retardation. Because of their tragic consequences, we dare not let down our guard against a resurgence of these diseases.

The President's Committee on Mental Retardation has brought to my attention an alarming decline of immunity levels among pre-school children. Last year more than 40 percent of these children were unprotected against either polio, measles, rubella, diphtheria, pertussis, or tetanus. On polio, for example, the Department of Health, Education, and Welfare Center for Disease Control reports that immunization levels dropped from 79 percent in 1963 to 60 percent in 1973.

Our children are America's future. Let us make that future a healthy one, for their sake and the Nation's sake.

NOW, THEREFORE, I, GERALD R. FORD, President of the United States of America, do hereby proclaim the week beginning October 20, 1974, as "Immunization Action Week," and call upon all parents, educators, and medical personnel to exert renewed efforts during this week and throughout the year to immunize every American child against diseases for which vaccines are available.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-first day of October, in the year of our Lord nineteen hundred seventy-four, and of the Independence of the United States of America the one hundred ninety-ninth.

/s/ GERALD R. FORD

[FR Doc.74—24889 Filed 10-21-74;3:56 pm]

FEDERAL REGISTER, VOL. 39, NO. 206—WEDNESDAY, OCTOBER 23, 1974